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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/563,024

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Dan Akerfeldt

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EXAMINER

BLATT, ERIC D

ART UNIT

PAPER NUMBER

3734

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/563,024	Applicant(s) AKERFELDT ET AL.	
	Examiner Eric Blatt	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 June 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,8,9 and 11-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,8,9 and 11-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 8, and 11-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Akerfeldt et al. (WO 00/78226) in view of Torgerson et al. (US 6,361,551) and Grafton et al. (US 2003/0050667).

Akerfeldt discloses a method and device (Figures 1-2) for sealing a puncture in a vessel, comprising a sealing element 2 configured to be placed against a wall of the vessel and to seal the puncture in the vessel by contacting the vessel wall, an outer member 3 configured to be placed outside of the vessel. Akerfeldt additionally discloses an elongated member comprising at least suture 6 and longitudinally extending post 7. The elongated member 6, 7 is configured to extend in an incision canal leading to the puncture in the vessel and hold together the sealing element and the outer member. Outer member 3 comprises a locking element 3 connected to the elongated member and adapted to be positioned against an outer surface of the vessel wall, and the sealing element is in the form of a plug. The inner member 2 comprises an anchor member 2 connected to the elongated member 6, 7. The outer member 3 comprises a second sealing element 3 having saw-teeth that fit into corresponding

recesses on a portion of the elongated member 6, 7 that extends through the second sealing element 3.

Akerfeldt fails to teach that the elongated member comprises threads not having haemostatic material surrounding a haemostatic core (Claim 1), the elongated member is coated with the haemostatic material (Claim 11), the elongated member is impregnated or soaked with the haemostatic material (Claim 12), or the elongated member is a multifilament comprising several filaments, each of which is coated with the haemostatic material (Claim 13). Akerfeldt additionally does not disclose that the haemostatic material is collagen.

Torgerson discloses a fiber (elongated member) wherein the elongated member comprises a haemostatic material (Columns 1-3), the elongated member is coated with the haemostatic material (Columns 1-3), the elongated member is impregnated or soaked with the haemostatic material (Columns 1-3), and the elongated member is a multifilament comprising several filaments, each of which is coated with the haemostatic material (Columns 1-3, Column 13, Lines 14-15). Additionally, Torgerson discloses that said haemostatic material is collagen. The fiber taught by Torgerson is entirely haemostatic and lacks the claimed threads that do not have haemostatic material surrounding the fiber. Grafton teaches improving strength and tie-down properties of a suture by providing a braided cover comprising braided polyethylene and polyester fibers over a core having a different material composition than the cover. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the Torgerson suture by providing the braided cover taught by Grafton over said suture in

order to provide a high strength fiber with improved tie down and haemostatic properties. So modified, the original Torgerson suture would comprise a haemostatic core, and the Grafton cover would act as an elongated capsule around said core. Further, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Akerfeldt by substituting the modified elongate member taught by Torgerson and Grafton for the elongated member 10 for purposes such as encouraging blood to coagulate, thereby preventing the vessel wall from leaking.

Akerfeldt does not disclose the elongated member having a diameter that is small—less than 25%, preferably less than 10%—in comparison to the diameter of the sealing element. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the dimensions of the elongated member and the sealing element since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claims 5 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Akerfeldt et al. (WO 00/78226) in view of Torgerson et al. (US 6,361,551) and Grafton et al. (US 2003/0050667) as applied to claims 4 and 8 above, and further in view of Kensey et al. (US 5, 531,759).

Akerfeldt, Torgerson and Grafton teach all elements of claims 5 and 9 as previously discussed except for the elongated member, plug, and locking

Art Unit: 3734

element/second sealing element comprising a haemostatic material. Kensey discloses a related closure device and teaches that it was known to provide a haemostatic agent blended into or coated upon the elongated member, the plug, the locking element, or any combination thereof. (Column 9, Lines 13-18) It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Akerfeldt by having the elongated member, the plug, and the locking element comprise a haemostatic material for purposes such as encouraging blood to coagulate, thereby preventing the vessel from leaking. So modified, said elements are configured to introduce haemostatic material into the incision canal to reduce secondary bleeding into the incision canal.

Response to Arguments

Applicant's arguments filed 9-18-2009 have been fully considered but they are not persuasive.

In defense of the novelty of the claimed haemostatic suture, Applicant first submits that nothing in the prior art is cited as addressing the problem of secondary bleeding. As discussed in the body of the rejection, the elongated member of the Akerfeldt reference is replaced with a fiber taught by Torgerson and Grafton which comprises a haemostatic core. As discussed in the Torgerson reference, the haemostatic material will reduce bleeding and promote healing at the surgical site. Thus, the device modified as discussed in the body of the rejection will reduce secondary bleeding as claimed.

Applicant further argues that Grafton would not suggest to one skilled in the art providing a braided cover over the Torgerson suture, submitting, "Grafton does not teach increasing the strength of a suture by providing a high strength cover over a core." To support this position, Applicant notes that the both the core and the cover of the Grafton suture comprise high-strength polyethylene materials, and that Grafton considers the cover to primarily provide improved tie down properties. In response, Examiner first notes that Grafton does teach providing a suture core with a braided cover having a different material composition than the core in order to provide the resulting suture with improved properties. Further, providing the Grafton cover over the Torgerson core would produce a suture having improved strength relative to the original Torgerson suture since the Grafton cover comprises high strength polyethylene. Finally, as Applicant has noted, the Grafton cover provides additional benefits to a suture including improved tie down properties. Examiner thus maintains that it would have been obvious to one of ordinary skill in the art to combine the Torgerson suture with the Grafton cover in order to produce a suture having improved strength, tie down and haemostatic properties.

Applicant additionally submits that nothing in the prior art is cited as teaching an 'elongated capsule.' The Grafton cover of the modified suture comprises an elongated capsule around the Torgerson core.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Hunter et al. (US 3,791,388) teaches a covered suture having a collagen core wherein the cover does not comprise collagen.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric Blatt whose telephone number is (571)272-9735. The examiner can normally be reached on Monday-Friday, 9:00 AM-6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

Art Unit: 3734

published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric Blatt/
Examiner, Art Unit 3734

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3734